



*Producers of Quality  
Nonprescription Medicines and  
Dietary Supplements for Self-Care*

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

*Formerly Nonprescription Drug Manufacturers Association*

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville, MD 20852

Re: Food Labeling: Use of Dietary Supplements of Health  
Claims Based on Authoritative Statements;  
64 Fed. Reg. 3250 (January 21, 1999); Docket No. 98N-0826

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA), formerly the Nonprescription Drug Manufacturers Association (NDMA), is the 118-year-old trade association representing manufacturers and distributors of dietary supplements and nonprescription medicines. The Association submits these comments in response to the above-referenced proposed rule concerning use on dietary supplements of health claims based on authoritative statements. FDA intends that its proposed rule would provide for the same process and standard for use on dietary supplements of health claims based on authoritative statements, as provided by section 403(r)(3)(c) of the act for conventional foods.

CHPA supports the agency's effort to place dietary supplements on an equal footing with conventional foods with respect to health claims based on authoritative statements. However, the Association does not agree that "significant scientific agreement" standard applies to these health claims.

### **I. The Approval Standard for Health Claims Based on Authoritative Statements**

FDA should only define the approval standard for health claims on dietary supplements or foods for those claims which are specifically submitted to FDA for promulgation of a health claims regulation. FDA does not have the legal authority to define the standard that would be used by other authoritative bodies to define statements/policies supporting health claims for dietary supplements or foods. Indeed, FDA's own wording for proposed §101.90(a) specifies that the claims under consideration in the proposed rule are those that are "not authorized by the Food and Drug Administration."

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The proposed rule cites and incorporates by reference a document entitled "Guidance for Industry—Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body."<sup>1</sup> 64 Fed. Reg. at 3252 (January 21, 1999). The agency says that the Guidance and nine interim final rules<sup>2</sup> reflect the agency's current thinking as to the process and principles that FDA will apply to the health claims based on authoritative statements.

In the referenced Guidance, FDA asserts that FDAMA "upholds the 'significant scientific agreement' standard for health claims"<sup>3</sup> based on authoritative statements because FDAMA permits FDA to issue a regulation that prohibits or modifies a claim based on the significant scientific agreement standard. FDA continues, saying, "consistent with this provision, FDA intends to determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement."<sup>4</sup>

Applying the significant scientific agreement standard to authoritative statements as provided in the Guidance would nullify and undermine the language and intent of Congress in the FDAMA authoritative statement health claims provision. FDA would place itself in the position of second-guessing and potentially overruling fellow government science agencies, which is exactly what Congress sought to change when it enacted the FDAMA authoritative statement provision.

Before FDAMA, health claims development was limited to the system provided in the Nutrition Labeling and Education Act (NLEA). Under the NLEA system, FDA gathers all public scientific evidence about a possible health claim. The agency then makes an independent determination whether there is "significant scientific agreement" among qualified experts that the health claim is supported.<sup>5</sup>

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<sup>1</sup> Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body, Office of Food Labeling, CFSAN, FDA; Notice of Availability, Docket No. 98D-0389, 63 Fed. Reg. 32101 (June 11, 1998); Internet at <http://www.cfsan.fda.gov/>.

<sup>2</sup> FDA published nine interim final rules based upon the Guidance in response to notifications of health claims based on authoritative statements. 63 Fed. Reg. 34084, 34092, 34097, 34101, 34104, 34107, 34110, 34112, and 34115 (June 22, 1998). CHPA does not address the nine interim final rules themselves.

<sup>3</sup> Guidance, note 1, *supra*.

<sup>4</sup> *Id.*

<sup>5</sup> The provision is as follows:

"The Secretary shall promulgate regulations authorizing [health] claims ... only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is *significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims*, that the claim is supported by such evidence."

Congress found this process to be seriously flawed because it failed to give sufficient weight to the authoritative statements of other government bodies with public health protection responsibility. The prime example cited by Congress was FDA's refusal from 1992 until 1996 to accept the Centers for Disease Control (CDC) determination about the relationship between folic acid and neural tube defects. Even though CDC was recognized for its authority and standing to issue scientific recommendations about public health matters, FDA would not accept the CDC folic acid/neural tube defect recommendation without a protracted rulemaking process. Congress said the process is "inefficient and fails adequately to benefit from the deliberative processes in which authoritative scientific bodies engage in issuing statements on matters of public health."<sup>6</sup>

To correct this problem, Congress developed an alternative mechanism intended to streamline and expedite health claims authorization. The alternative process gives proper weight to the authoritative statements of other federal science bodies such as CDC, without FDA reexamination of the underlying scientific evidence. Under the alternative system, codified in FDAMA, Congress permits health claims to be made based upon duly authorized statements from federal bodies other than FDA with public health responsibility, where FDA has been given premarket notification about the claim. The provision states that a health claim "shall be authorized and may be made" if:

"[A] scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers." 21 U.S.C. § 343(r)(3)(C).

A health claim that meets these criteria for an authoritative statement is presumptively valid under the statute. There is no basis for an independent FDA review of the science that has already been reviewed by another federal government science body. FDA reexamination of the claim under the NLEA significant scientific agreement standard would basically bootstrap the NLEA standard and procedure into the FDAMA procedure. It would mean that the agency could substitute its own judgment for the authoritative

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<sup>6</sup> Report of the Committee on Labor and Human Resources on S. 830 at 49 (July 1, 1997).

statement of another federal government body, effectively gutting the FDAMA provision. This would produce a repetition of the problem represented by the folic acid situation, which the FDAMA provision was intended to correct.<sup>7</sup>

Under FDAMA, FDA has the ability to supersede an authoritative statement health claim if it independently issues a regulation “prohibiting or modifying the claim” under the significant scientific agreement standard of section 403(r)(B)(i). This is different, however, from FDA’s ability to publish a health claim regulation based upon a health claim petition filed under the NLEA. The FDAMA provision cannot be read to permit FDA to approve a health claim based on an authoritative statement only where the agency would be prepared to approve an NLEA health claim petition under the significant scientific agreement standard. To do so would transform the authoritative statement health claims provision of FDAMA into a virtual clone of the NLEA health claims provision, nullifying the FDAMA provision.

The federal courts have also made clear that under the First Amendment commercial speech doctrine, FDA may not suppress health claims that are truthful and not misleading. In Pearson v. Shalala, the U. S. Court of Appeals held that health claims enjoy First Amendment commercial speech protection, and it rejected FDA’s arguments that health claims are inherently misleading unless they are pre-approved by the agency based on a “significant scientific agreement” standard. No. 98-5043, slip op. (D.C. Cir., Jan. 15, 1999).<sup>8</sup> It is clear under the Pearson decision that truthful claims based upon the authoritative statements of federal scientific bodies, including qualified statements concerning diet/disease relationships, not only must be authorized under FDAMA but are constitutionally protected under the First Amendment. To the extent that the FDA Guidance document would import the significant scientific agreement standard from the NLEA health claims provision into the authoritative statement health claims provision barring truthful and nonmisleading qualified claims, the Guidance document is invalid under Pearson v. Shalala, and should be revoked or revised.

In sum, FDA should not attempt to impose its authority over other government agencies charged with public health protection by defining an over-arching standard that it would administer to approve all health claims. At the most, FDA should only define its own approval standard for health claims based on applications submitted for FDA health

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<sup>7</sup> While CHPA maintains that the significant scientific agreement standard does not apply to authoritative statement health claims under § 343(r)(3)(C), the Association notes that the U.S. Court of Appeals for the D.C. Circuit recently invalidated four FDA health claims regulations for dietary supplements issued under § 343(r)(3)(B), on the grounds, in part, that FDA violated the Administrative Procedure Act by failing to define the standard. Pearson v. Shalala, No. 98-5043 (D.C. Cir., Jan. 15, 1999).

<sup>8</sup> The court also found that the agency had failed to define “significant scientific agreement” and therefore violated the Administrative Procedure Act. Id. at 20.

claims regulations. The following section specifies those aspects of the proposed § 101.90 that should be amended to conform with CHPA's recommendations.

## **II. The Process for Approval of Health Claims Based on Statements from Authoritative Bodies**

FDA proposed to add a new section to subpart E of § 101 (101 CFR 101) to provide for the use of health claims based on statements from authoritative bodies, in order to place dietary supplements on an equal footing with conventional foods with respect to health claims.

CHPA agrees with the basic approach of proposed § 101.9(a) – (b), including the following basic points:

1. Per FDA's proposal, proposed § 101.90(a) should apply to health claims based on authoritative statements that are "not authorized by FDA" (see page 3254 of the Federal Register proposal, middle column). Therefore, FDA should not attempt to define a preemptive approval standard.
2. The authoritative statement from a scientific body of the U.S. government with official responsibility for public health protection should be "currently in effect" [see proposed § 101.90(a)]. CHPA believes FDA should define the term "currently in effect" in the preamble to the Final Rule or in a guidance, stating that the term means that the statement from a sanctioned authoritative body, including FDA, represents the current published public policy of that agency on the specified health issue relating to, for example, dietary supplements and not a statement of an employee of the scientific body made in the individual capacity of the employee.

CHPA recognizes that this concept is found in proposed § 101.90(a)(4). However, the Association believes that the relevant concepts (i.e., "currently in effect," "published policy;" and "not a statement of an employee...in the individual capacity of the employee") should be consolidated in one place for the purposes of facilitating compliance policy.

3. The 120-day pre-notification process cited in proposed § 101.90(a)(2) should be regarded, as specified in the proposal, as a period of time during which FDA may notify the submitter that not all the information specified in proposed § 101.90 has been submitted. This should not be construed by the agency or any other party as an approval period for FDA's review of a health claim statement from another sanctioned authoritative body.

CHPA believes that this distinction, between FDA's approval of a health claim within a 120 day period and FDA's review as to whether all the information has been submitted for a health claim based on a statement from other authoritative bodies, should be made in the preamble and in any guidance that might be developed or revised in relation to this general issue.

4. The submission of a health claim based on a statement from an authoritative body should include, per proposed § 101.90(a)(2):
  - A notice of the claim [see proposed § 101.90(a)(2)(i)];
  - A copy of the statement [see proposed § 101.90(a)(2)(ii)];
  - A balanced presentation of the scientific literature [see proposed § 101.90(a)(2)(ii)];
  - The statement of the claim and dietary supplement in conformance with § 101.14(a)(5) and (c)(3) and sections 403(a) and 201(n) of the act [21 USC 343(a) and 21USC 321(n); see proposed § 101.90(a)(3)];
  - The statement of the claim in a manner that is an accurate presentation of the authoritative statement that is the subject of the submission, so that the public can comprehend the information and be able to understand the relative significance of such information in the context of a total daily diet [see proposed §101.90(a)(4)].

Finally, in terms of proposed §101.90(b) relating to FDA's ability to issue a regulation prohibiting or modifying a health claim, CHPA requests that FDA modify proposed §101.90(b) to specifically state that any prohibition or modification of a health claim based on a statement from another sanctioned authoritative body will first rely on the prohibition or modification of that statement by that sanctioned body, not by an action initiated by FDA prior to consideration of the statement by the other authoritative body. As stated in Section I of these remarks (see above), Congress found the pre-FDAMA system of FDA approval of health claims seriously flawed because it failed to give sufficient weight to the authoritative statement of other government bodies. We cited the prime example that led to Congress' concern as CDC's determination that folic acid can prevent neural tube defects. To permit in regulation, as found in proposed § 101.90(b), provisions that would allow FDA independently to supercede the public policy statements of other sanctioned authoritative bodies would to undermine the intent of Congress in this area.

Thus, FDA should specifically clarify that it will not "second guess" the public policy of another sanctioned authoritative body by undertaking a review of that body's policy that is "currently in effect." It should be the responsibility of the authoritative body that created the public policy statement supporting the health claim to revise its policy before FDA prohibits or modifies the health claim. Once that is done, then FDA has the legal authority to prohibit or mandate the claim. If the health claim has been originally

submitted for issuance of an FDA health claim regulation, then FDA would have the responsibility to prohibit or amend the health claim. Specifically, proposed § 101.90(b) should be amended as follows (i.e., the underlined language below represents language CHPA requests be added to the Final Rule):

Re: Proposed § 101.90 (b)

“(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

“(1.) Such time as FDA issues a regulation under the standard in § 101.14(c):

“(i) Prohibiting or modifying the claim and the regulation has become effective, providing that, if the claim is based on a statement from authoritative body other than FDA, that body has made a determination that its statement supporting the health claim should be modified or amended;

or

“(ii) Finding that the requirements of paragraph (a) of this section have not been met, including finding that the petitioner has not submitted all the information required by such clause and, if applicable, section (i) of this section has been met ; or

“(2) A District Court of the United States in an enforcement proceeding under chapter III of the act (21 USC 301-310) has determined that the requirements of paragraph (a) of this section has not been met.”

### **III. Summary**

In summary, CHPA requests the following changes in concept and content of the agency's proposal to create the same standard and process for use on dietary supplements of health claims based on authoritative statements, as provided by section 403r(3)(c) of the act for conventional foods:

1. The Final Rule should reflect Congress' intent under FDAMA that there be an alternative mechanism to NLEA for health claims for dietary supplements, since the development of health claims has been shown to be susceptible to protracted rulemaking process (e.g., the health claim for folic acid and neural tube defects).
2. In order to streamline and expedite health claims development, FDA should not attempt to impose its authority over other government agencies charged with public health protection by defining an over-arching standard that it would administer to

approve all health claims. At the most, FDA should only define its own approval standard for health claims based on applications submitted for an FDA health claim regulation.

3. CHPA agrees with the basic approach of proposed § 101.9(a) – (b), but makes specific recommendations about the wording to reflect in the Final Rule a process that would facilitate and therefore not thwart health claims development, including:

- Per FDA's proposal, proposed § 101.90(a) should apply to health claims based on authoritative statements that are "not authorized by FDA;" therefore, FDA should not attempt to define a preemptive approval standard;
- CHPA recognizes that the concept of "currently in effect" is partially addressed in proposed § 101.90(a)(4); however, the Association believes that the relevant concepts (i.e., "currently in effect," published policy;" and "not a statement of an employee...in the individual capacity of the employee") should be consolidated in one place for the purposes of facilitating compliance policy;
- CHPA believes that the distinction between FDA's approval of a health claim within a 120 day period and FDA's review as to whether all the information has been submitted for a health claim based on a statement from other sanctioned authoritative bodies should be made in the preamble and in any guidance that might be developed or revised in relation to this general issue;
- CHPA agrees with the basic provisions of proposed § 101.90(a)(2);
- CHPA requests that FDA modify proposed §101.90(b)i) and (ii) to specifically state that any prohibition or modification of a health claim based on a statement from another sanctioned authoritative body will first rely on the prohibition or modification of that statement by that sanctioned body, not by an action initiated by FDA prior to consideration of the statement by the other authoritative body as follows (new language underlined below):

“(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

“(1.) Such time as FDA issues a regulation under the standard in § 101.14(c):

“(i) Prohibiting or modifying the claim and the regulation has become effective, providing that, if the claim is based on a statement from authoritative body other than FDA, that body has made a determination that its statement supporting the health claim

should be modified or amended;

or

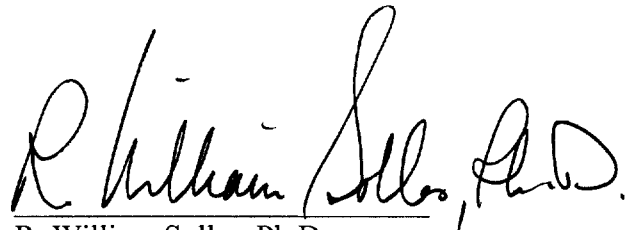
“(ii) Finding that the requirements of paragraph (a) of this section have not been met, including finding that the petitioner has not submitted all the information required by such clause and, if applicable, section (i) of this section has been met ;”

CHPA offers these comments in the spirit of cooperation with the agency in order to achieve the best possible final rule for the health benefit of consumers. Should you wish any clarification to these comments, please do not hesitate to reach either of us at CHPA (telephone number 202-429-9260).

Respectfully submitted on behalf of  
the CHPA Dietary Supplement Strategic Planning Group  
by:



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~~General Administrative Issues should be made in the preambles of any guidance that~~  
might be developed or revised in relation to this general issue;

- CHPA agrees with the basic provisions of proposed § 101.90(a)(2);
- CHPA requests that FDA modify proposed §101.90(b)i) and (ii) to specifically state that any prohibition or modification of a health claim based on a statement from another sanctioned authoritative body will first rely on the prohibition or modification of that statement by that sanctioned body, not by an action initiated by FDA prior to consideration of the statement by the other authoritative body as follows (new language underlined below):

“(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

“(1.) Such time as FDA issues a regulation under the standard in § 101.14(c):

“(i) Prohibiting or modifying the claim and the regulation has become effective, providing that, if the claim is based on a statement from authoritative body other than FDA, that body has made a determination that its statement supporting the health claim